

6-28-2016

A Clinical Trial To Investigate Digital Gingivitis Image Analysis Method and Examiner-Based Grading in Assessing Experimental Gingivitis

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Recommended Citation

Aranguren, Liliana E., "A Clinical Trial To Investigate Digital Gingivitis Image Analysis Method and Examiner-Based Grading in Assessing Experimental Gingivitis" (2016). *Master's Theses*. 1001.
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A Clinical Trial to Investigate Digital Gingivitis Image Analysis Method and
Examiner-Based Grading in Assessing Experimental Gingivitis

Liliana Aranguren

D.D.S., Universidad del Zulia, 2002

A Thesis

Submitted in Partial Fulfillment of the

Requirement for the Degree of

Master of Dental Science

at the

University of Connecticut

2016

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2016

APPROVAL PAGE

Master in Dental Science Thesis

A Clinical Trial to Investigate Digital Gingivitis Image Analysis Method and Examiner-
Based Grading in Assessing Experimental Gingivitis

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2016

DEDICATION

I dedicate this thesis to my wonderful family. You have allowed me to fulfill my dream of becoming a periodontist and for that I will be forever grateful.

To my parents, Jesus and Talula, whose appreciation and respect for education has guided and driven me to succeed. Without the constant support and prodding of my mother, I would not be here today.

Finally, to my brother Che and my sisters Keyna and Zaire, I thank each of you for all the support and guidance for me throughout this long journey. You are all so unique and have helped shape me into the individual I am today.

ACKNOWLEDGMENTS

I would like to thank my thesis committee for all their efforts and guidance during this entire process. Thank you Dr. Ioannidou, for your supervision and direction from the very beginning and for your willingness to take me on this project, from overseeing this research topic to approving the final version of this thesis. This project would not have been possible without your support and belief in me. Your effort, cheerful demeanor, and friendly advice are appreciated more than you will ever know.

Thank you Dr. Diaz, for being the present source of help and consultation for all the periodontics questions that arose throughout this project. It has been an honor and privilege to study under your guidance.

Thank you Dr. Uribe, for being part of the project, for always supporting me and for trusting me with your precious patients.

I am very grateful for the support provided by all professors at the Division of Periodontology at the University of Connecticut. The program without doubts made me grow not only as a clinician but also most importantly as a person. To Dr. Schincaglia, my eternal gratitude for your limitless dedication and commitment to our education.

Thank you Dr. Mathew Barker, for all your help in analyzing and interpreting the statistics for the study.

Finally, I would like to thank Mrs. Megyn Clement for all the help during the study and P&G for the generous donation of equipment for each of the subjects participating in this project. Without your support, this project could never have been initiated.

TABLE OF CONTENTS

TITLE PAGE.....	i
COPYRIGHT PAGE.....	ii
APPROVAL PAGE.....	iii
TABLE OF CONTENTS.....	iv
DEDICATION.....	v
ACKNOWLEDGMENTS.....	vi
ABSTRACT.....	vii
1. Introduction.....	1
2. Background and Significance.....	3
2.1 Gingivitis.....	3
2.1.1 Definition and Prevalence.....	3
2.1.2 Etiology.....	5
2.1.3 Histopathology.....	6
2.1.4 Experimental Gingivitis.....	7
2.1.4 Clinical Assessment of Gingivitis.....	9
2.1.4.1 Gingival Indices.....	10
2.2 Digital Imaging System.....	17
3. Aim, Hypothesis and Objectives.....	18
3.1 Aim.....	18
3.2 Hypothesis.....	18
3.3 Objectives.....	19
4. Study Design and Methods.....	19
4.1 Study Design.....	19
4.2 Population.....	19
4.3 Experimental Design and Procedures.....	21
5. Results.....	31
6. Discussion.....	41
7. Conclusion.....	44
8. References.....	45

A Clinical Trial to Investigate Digital Gingivitis Image Analysis Method and
Examiner-Based Grading in Assessing Experimental Gingivitis

Liliana Aranguren D.D.S

University of Connecticut, 2016

Objective: To compare a Digital Gingivitis Image Analysis (DGIA) method and examiner-based gingival grading in assessing experimental anterior gingivitis.

Methods: This was a single-center, examiner-blinded, parallel-group, randomized clinical trial. The study had 49 subjects (26 females and 23 males; mean age of 32 years) and consisted of 2 phases: two-week Oral Hygiene phase and three-week induced gingivitis phase (days 0-21). During the hygiene phase, subjects received an oral prophylaxis and used an electric toothbrush with regular toothpaste. At day 0 of the Induced Gingivitis phase, 25 patients were randomly selected into the power brush group, which brushed twice daily. 22 Subjects, which abandoned all oral hygiene, were randomly selected into the “no hygiene” (control) group. Both control and experimental groups received an oral prophylaxis at day 21. Gingivitis was assessed via Loe-Silness examinations (LSGI) and Digital Gingivitis Image Analysis at days -14, 0, 14 and 21.

Results: Groups were balanced ($p > 0.4$) with respect to demographics and gingivitis scores. At day 0, mean LSGI was 1.20 and mean number of bleeding sites was 40.49. Statistically significant ($p < 0.001$) differences in frequency of gingivitis were observed between the groups at days 14 and 21.

At day 21, LSGI adjusted means were 1.16 and 1.56 for the power brush and the “no hygiene” group, respectively, corresponding to a 25% difference. Adjusted means for number of bleeding sites was 36.25 for power brush and 91.25 for the “no hygiene” group, corresponding to a 60% difference. Using the imaging system we noticed the marked changed in color from day 0 to day 21. We observed 2 units of color change ($\Delta E_{2000} = 2.41$) for non-brushing group and 1.4 units change on brushing group ($\Delta E_{2000} = 1.41$). These changes were consistent with the clinical measurements.

Conclusion: The present study using the short-term, induced gingivitis model demonstrated Digital gingivitis image analysis positively associates with clinical parameters in an experimental gingivitis model.

1. Introduction

Gingivitis and periodontitis are the two major forms of inflammatory diseases affecting the periodontal apparatus. Their primary etiology is bacterial plaque, which can start the destruction of the gingival tissues and periodontal attachment lost (AAP 1999). Gingivitis is an inflammatory lesion of the gingival tissues, which usually precedes periodontitis (Waerhaug, 1966). It has been shown to be reversible (Löe et al., 1967) and, although progression is not predictable, the prevention of gingivitis is still the first step toward preventing periodontitis (Burt et al., 2005).

In the first U.S. national survey of adults in 1960-62, which scored gingivitis visually, 85% of men and 79% of women were found to have some degree of gingivitis. More recent epidemiological evidence suggested that, gingivitis affects more than 50% of the United States (U.S.) adults (Albandar 1999, Eke 2015). In large population studies, gingivitis diagnostic criteria may need to be properly defined, in order to allow the cross-sectional comparisons between different population groups, as well as to determine risk factors, and evaluate treatment efficacy (Benamghar et al., 1982). Therefore, it has been suggested (Scannapieco, 2004) that the prevalence of gingivitis might be understated depending on clinical quantitative cutoffs.

Quantitative disease measurements are commonly based on indices systems. An efficient index system was expected to be quick, reproducible and user-friendly involving minimal instrumentation and accurately reflecting degrees of pathology (Engelberger, 1983). Numerous gingival indices have been utilized over the years in epidemiology and oral product assessment studies (Ciancio 1986). These indices have been based on evaluation

of gingivitis clinical features including edema, color, contour, bleeding and gingival crevicular fluid. Bleeding indices are often considered more objective with greater clinical relevance than assessments of gingival appearance as a measure of gingivitis.

The Gingival Index (Löe and Silness, 1963) was created for the assessment of the gingival condition and records qualitative changes in the gingiva. It scores the marginal and interproximal tissues separately on the basis of 0 to 3. The criteria were: 0 = Normal gingiva; 1 = Mild inflammation – slight change in color and slight edema but no bleeding on probing; 2 = Moderate inflammation – redness, edema and glazing, bleeding on probing; 3 = Severe inflammation – marked redness and edema, ulceration with tendency to spontaneous bleeding. Probing gently along the wall of the gingival sulcus assesses the bleeding. The scores of the four areas of the tooth can be summed and divided by four to give the GI for the tooth. Adding the values of each tooth and dividing by the number of teeth examined the GI of the individual is obtained. The Gingival Index may be scored for all surfaces of all or selected teeth or for selected areas of all or selected teeth. The GI may be used for the assessment of prevalence and severity of gingivitis in populations, groups and individuals. Although GI is a nominal variable, it has been treated as a continuous variable since it was introduced by Loe (1963) with statistical consequences. Therefore, a score from 0.1-1.0 = mild inflammation; 1.1-2.0 = moderate inflammation from, and 2.1-3.0 signifies severe inflammation. The GI has been frequently used in clinical trials of therapeutic agents. The sensitivity and reproducibility is good provided the examiner's knowledge of periodontal biology and pathology is optimal (Löe, 1967).

As GI relies on subjective assessment by a trained examiner using non-linear numerical scales (i.e. where a score of 2 does not necessarily indicate twice the severity of a score

of 1), it is subject to intra- and inter-examiner variability (McClanahan 2001). Therefore, it is highly desirable to have an objective, quantitative technique for assessing gingival clinical condition. Recently, researchers have evaluated the use of imaging techniques to assess gingivitis (Smith et al. 2008, Biesbrock et al. 2009). However, the studies inherited many limitations including small sample size and/or the lack of blindness and randomization.

As the electronic measurement of gingival color by digital image is a non-invasive reproducible inexpensive method of assessment, photographic methods have been applied in the assessment of gingival overgrowth. Standardized photographic view was evaluated against a reference set of photographs of various degrees of gingival overgrowth (Hefti et al. 1994). Assessment by photography has advantages for large-scale studies including: 1) no need for dental chair setting; 2) no need for dental invasive procedures, such as impressions taken; 3) utilization of trained and calibrated auxiliary personnel such as a dental assistant or dental hygienist.

Therefore, as photography and digital imaging may be utilized in public oral health and clinical practice, there is a need to assess the reliability and objectivity of digital imaging in gingivitis diagnosis.

2. Background and Significance

2.1 Gingivitis

2.1.1 Definition and Prevalence

Gingivitis is defined as the presence of gingival inflammation without the loss of connective tissue attachment (Armitage, 1995).

The characteristics of biofilm-induced gingivitis according to Mariotti (1999), are: (1) microbial biofilm present at gingival margin; (2) change in gingival color; (3) change in gingival contour; (4) sulcular temperature change; (5) increased gingival exudate; (6) bleeding upon provocation; (7) absence of attachment loss; (8) absence of bone loss; and (9) histological changes. The clinical signs and symptoms will vary between individuals as well as the different sites of the dentition in the same subject.

The 3rd National Health and Nutrition Examination Survey (NHANES III) conducted in 1988-1991 gives us some measure to determine the prevalence of gingivitis. However, NHANES III did not directly attempt to quantify gingivitis. The data collected included bleeding on probing, which we can then correlate to a moderate inflammation using the index for assessment of gingivitis introduced by Løe and Silness in 1963. The periodontal evaluation in NHANES III included a total of 7,447 individuals 13 years and older. The examinations were partial-mouth periodontal exams, performed on two randomly selected quadrants, on 2 sites per tooth, with a maximum of 14 permanent teeth eligible for assessment (third molars were excluded). Brown et al. 1996, reported that bleeding on probing was found in 62.9% for all persons aged 13 and older. However, these data have to be considered with caution, since a partial-mouth periodontal assessment has been shown to underestimate the prevalence of the disease (Susin et al 2005). Furthermore, the criteria to detect gingivitis include the visible signs of color change and texture. Thus, a large percentage of individuals with gingivitis without bleeding on probing were not included in the above statistic. A recent study by Li et al. 2010 sought to determine the prevalence of gingivitis in American adults using the Løe and Silness Gingival Index (GI) and found that 93.9% of individuals had a mean GI >

0.50. This percentage decreased to 55.7% for individuals with a mean GI ≥ 1.0 . These studies suggest that the prevalence of gingivitis in the American population range between 55.7% and 93.9% depending on the definition used and method of calculation.

2.1.2 Etiology

The etiology of gingivitis was well demonstrated by L  e in 1963. In this study, a direct relationship was found between plaque accumulation and gingival inflammation. Hence, this study offered proof that bacterial biofilm causes gingivitis (Loe et al 1965).

Under experimental gingivitis conditions, a significant shift was observed in the bacterial composition from health to gingivitis (Loe et al. 1965). The bacteria of healthy gingiva were composed mainly of gram-positive cocci and rods. When localized gingivitis was first clinically detectable (GI = 1 on one tooth surface), gram-negative cocci and rods were found in increasing percentages in the microflora. There was a shift again as generalized gingivitis was clinically identified (GI = 1 for the individual). Here, gram-positive and negative filaments, fusobacteria, spirilla, and spirochetes were more readily measurable. In another study (Theilade et al. 1966) a correlation between gingival status and plaque composition was established. In this study the growing complexity of the microflora composition as plaque accumulates was demonstrated. The results indicated that gingivitis is not due to an infection of a single pathogen, but rather a plaque ecology that is unfavorable to the host (Theilade 1986).

2.1.3 Histopathology

The histological features of healthy gingiva include a keratinized oral epithelium continuous with a junctional epithelium that is attached to the tooth surface by hemidesmosomes. Small amount of Polymorphonuclear leukocytes, are present in the healthy sulcus as a normal reaction to the biofilm present around teeth even in meticulously cleaned mouth (Page and Schroeder, 1976). If sufficient plaque is allowed to accumulate, gingivitis will occur. The first stage of gingivitis is the *initial lesion*. It is formed within 2-4 days of the initiation of plaque accumulation. The characteristics of the initial lesion are vasculitis adjacent to the JE, increased flow of gingival crevicular fluid and increased migration of PMNs into the JE and sulcus. Additionally, an altered morphology of epithelial cells in the coronal part of the JE and loss of perivascular collagen can be seen. Neutrophils adhere to vessel walls and migrate to the connective tissue, JE, and sulcus. At this stage bacterial invasion is not evident and the inflammatory response seems to be related to plaque-derived chemotactic substances (Page and Schroeder, 1976).

The second stage of gingivitis is called the *early lesion*. It is mostly an accentuation of the initial lesion and occurs at days 4 through 7. There is an accumulation of lymphoid cells (approximately 75% of the total infiltrate) adjacent to the JE, further loss of collagen fiber network supporting the marginal gingiva and the beginning of proliferation of the basal cells of the JE. The primary distinguishing feature is the migration of lymphoid cells (predominately T cells with very few B cells) into the lesion (Page and Schroeder, 1976). The third and final stage of gingivitis is the *established lesion*. It is formed at least 7 days after the initiation of plaque accumulation. The histo-pathological hallmark of this

condition is the predominance of *plasma cells*. Immunoglobulins are seen extravascularly in the connective tissues and JE. There is a continuing loss of connective tissue matrix elements and proliferation, apical migration, and lateral extension of the JE leading to the formation of a pocket epithelium (Page and Schroeder, 1976). This established lesion could remain stable for months or years without progressing. The *established lesion* is still reversible. Further persistence of the established lesion may eventually progress to the *advanced lesion*, which is defined as irreversible and accompanied by attachment loss. Once attachment loss occurs, the condition is defined as periodontitis.

2.1.4 Experimental Gingivitis

The model of experimental gingivitis, which requires patients to refrain from oral hygiene measures for a period of time, was first proposed by Loe et al. in 1965. In this study, experimental gingivitis was achieved by removing all oral hygiene practices for 21 days in healthy subjects. The development of gingivitis varied by individual and occurred as early as 10 days in some subjects. By day 21 all participants showed clinical signs of gingivitis. Following the experimental phase, oral hygiene practices were reinstituted resulting in the return to health in about 1 week (Loe et al. 1965).

The experimental gingivitis model has been used universally over the past 50 years to measure a variety of outcome variables. One of these outcome variables is whether age plays a role in susceptibility to gingivitis. In an experiment by Holm-Pedersen et al. 1975, gingivitis developed more rapidly and more severely in elderly than in young persons. The authors suggest that with age comes an altered host response to the bacterial plaque. The effect of age on the host response to plaque accumulation was confirmed by Matsson

in 1978, who compared pre-school aged children with young adults. The author found that the younger group had a statistically significantly lower amount of gingival exudate and gingival bleeding than the older group. Winkel et al. 1987 tested the effect of age on the rate of development of gingivitis in persons not susceptible to periodontal destruction. The study showed was that in individuals not susceptible to periodontal destruction, age was not a factor in the development of experimentally induced gingivitis. Winkel et al. and Matsson used different classifications of age, making direct comparisons of both studies difficult. Thus, there may be a critical age difference required to detect a true difference in gingivitis susceptibility to plaque accumulation.

The experimental gingivitis model has also been used to elucidate the histopathologic and immunologic features of gingival inflammatory changes. Payne et al. 1975 used the experimental gingivitis model to describe the pathologic alterations in gingival tissues in early plaque accumulation. They found that within the first 8 days of plaque accumulation, a lesion resembling a delayed hypersensitivity developed. Seymour et al. 1983 obtained biopsies at four time points through a 21-day oral hygiene abstention study and found that the nature of the composition of the infiltrate did not change significantly, as the degree of inflammation increased.

The early experimental gingivitis studies hinted at the possibility of differences in subject susceptibility to plaque accumulation. This response variability was interpreted as related to differences in plaque accumulation rates or differences in microbial composition (Loe et al 1965, Theilade et al. 1966). More recently, Trombelli et al. 2004 in an experimental gingivitis trial was able to identify two subgroups of subjects that differed in their response to similar plaque exposure. These were labeled the “High Responder” and “Low

Responder”. The identification of these two subpopulations was based on their amount of GCF volume. This finding supports the hypothesis of the existence of host-related factors implicated in the individual variability of the inflammatory response to plaque. The implication of susceptibility to gingivitis due to a subject’s genetic make-up or host response versus a purely microbial reaction has changed how the disease process is studied. More efforts are looking into the effect of genetic variation and other factors that could further elucidate the pathogenesis of gingivitis.

2.1.4 Clinical Assessment of Gingivitis

Quantitative measurement of disease is mostly based on indices systems. Several gingival indices have been proposed in literature, all of which have relied on one or more of the following criteria: gingival color (redness), gingival contour, gingival bleeding, gingival stippling and gingival crevicular fluid flow (Ciancio, 1986; Fischman, 1988; Newbrun, 1996). These clinical features can be assessed visually, (e.g., color, contour, spontaneous bleeding) and/or invasively, with the use of an instrument (e.g., bleeding on provocation). Whereas some of the indices include both visual and invasive components, others are based on either visual feature alone or bleeding on provocation alone. Thus, gingivitis can be evaluated by either quantitative clinical indices that are based on a combination of inflammation symptoms or extent of gingival involvement or on bleeding as a single variable (Barnett, 1996; Lorenz et al., 2009). Moreover, many investigators have used variations of "present or absent" indices which do not consider the severity of gingival inflammation. The observation of whether or not inflammation is present in the gingiva might be a useful approach in clinical studies. Such an index would be simple,

reproducible with little examiner training and require relatively little time (Hazen, 1974). Although several indices have been proposed, with many different methodologies, no one has universal application or acceptance (table 1)

2.1.4.1 Gingival Indices

PMA Index

The PMA index was developed by Schour & Massler (1947) and described by Massler (1967). It is probably the first successful attempt to design a numerical system for recording gingival health. The index scores gingival units as separate entities and is based on the premise that inflammation commences in the interdental papilla from where it spreads to the marginal and ultimately the attached gingiva. Each gingival unit is scored on the basis of 0-4. Only the labial surfaces are examined. The number of affected Papillary, Marginal and Attached units are counted for each individual and recorded. Its major purpose has been the evaluation of gingival inflammation in children.

Gingival Index (GI)

The Gingival Index (Löe and Silness, 1963) was created to assess the gingival condition and records qualitative changes in the gingiva. It scores the marginal and interproximal tissues separately on the basis of 0 to 3. The criteria are: 0 = Normal gingiva; 1 = Mild inflammation – slight change in color and slight edema but no bleeding on probing; 2 = Moderate inflammation – redness, edema and glazing, bleeding on probing; 3 = Severe inflammation – marked redness and edema, ulceration with tendency to spontaneous bleeding. The bleeding is assessed by probing gently along the wall of soft tissue of the

gingival sulcus. The scores of the four areas of the tooth can be summed and divided by four to give the GI for the tooth. The GI of the individual can be obtained by adding the values of each tooth and dividing by the number of teeth examined. The GI may be used for the assessment of prevalence and severity of gingivitis in populations, groups and individuals. A score from 0.1-1.0 = mild inflammation; 1.1-2.0 = moderate inflammation from, and 2.1-3.0 signifies severe inflammation.

Sulcus Bleeding Index (SBI)

An early sign of gingivitis is bleeding on probing and, in 1971; Muhlemann and Son described the Sulcus Bleeding Index (SBI). The criteria for scoring are as follows:

Score 0 – health looking papillary and marginal gingiva no bleeding on probing;

Score 1 – healthy looking gingiva, bleeding on probing;

Score 2 – bleeding on probing, change in color, no edema;

Score 3 – bleeding on probing, change in color, slight edema;

Score 4 –bleeding on probing, change in color, obvious edema;

Score 5 –spontaneous bleeding, change in color, marked edema.

Four gingival units are scored systematically for each tooth: the labial and lingual marginal gingival and the mesial and distal papillary gingival. Scores for these units are added and divided by four. Adding the scores of the undivided teeth and dividing them by the number of teeth can determine the sulcus-bleeding index.

Gingival Bleeding Index (GBI)

In 1974, Carter and Barnes introduced a Gingival Bleeding Index, which records the presence or absence of gingival inflammation after passing unwaxed dental floss into the proximal sites. It is readily available, disposable, and can be used by the instructed patient for self-evaluation. The mouth is divided into six segments and flossed in the following order; upper right, upper anterior, upper left, lower left, lower anterior and lower right. Bleeding is generally immediately evident in the area or on the floss; however, thirty seconds is allowed for reinspection of each segment. Bleeding is recorded as present or absent. For each patient a Gingival Bleeding Score is obtained by noting the total units of bleeding and the total susceptible areas at risk.

Gingival Bleeding Index (GBI - Ainamo & Bay, 1975)

This Gingival Bleeding Index (GBI), introduced by Ainamo & Bay (1975), is performed through gentle probing of the gingival crevice. If bleeding occurs within 10 seconds a positive finding is recorded and the number of positive sites is recorded and then expressed as a percentage of the number of sites examined. It has been shown that the scores obtained with this index correlate significantly to GI (Löe and Silness, 1963) and has been used in profile studies and short-term clinical trials.

Papillary Bleeding Index (PBI)

The Papillary Bleeding Index was first introduced by Saxer and Muhlemann (1975), as cited by Muhlemann (1977). This index is based upon the actual bleeding tendency of the gingival papillae. A periodontal probe is inserted into the gingival sulcus at the base of

the papilla on the mesial aspect, and then moved coronally to the papilla tip. This is repeated on the distal aspect of the papilla. The intensity of any bleeding is recorded as:

Score 0 – no bleeding;

Score 1 – A single discrete bleeding point;

Score 2 – Several isolated bleeding points or a single line of blood appears;

Score 3 – The interdental triangle fills with blood shortly after probing;

Score 4 – Profuse bleeding occurs after probing; blood flows immediately into the marginal sulcus.

Modified Papillary Bleeding Index (MPBI)

Barnett et al. (1980) modified the PBI index (Muhlemann, 1977) by stating that the periodontal probe should be gently placed in the gingival sulcus at the mesial line angle of the tooth surface to be examined and carefully swept forward into the mesial papilla.

They timed the appearance of bleeding and graded it as follows:

0 = no bleeding within 30 s of probing;

1 = bleeding between 3 and 30 s of probing;

2 = bleeding within 2 s of probing;

3 = bleeding immediately upon probe placement.

The mesial papillae of all teeth present from the second molar to the lateral incisor were assessed. Indices were derived for the maxillary left and mandibular right buccal segments, and the maxillary right and mandibular left lingual segments, and from these a full-mouth index was calculated. They showed that the modified PBI might be more sensitive than the visual aspects of the GI in assessing changes in gingival health.

Bleeding Time Index (BTI)

Nowicki et al. (1981) proposed that a gingival index bleeding would be useful for detecting the first clinical evidence of gingival inflammation. The method consisted of inserting a Michigan “0” probe in the sulcus until slight resistance was felt and then the gingiva was stroked back and forth once over an area of approximately 2 mm. The following scores are applied:

0= no bleeding within 15 seconds of second probing (i.e. 30 seconds total time);

1= bleeding within 6 to 15 seconds of second probing;

2= bleeding within 11 to 15 of seconds of first probing or 5 seconds after second probing;

3= bleeding within 10 seconds after initial probing

4= spontaneous bleeding.

Eastman Interdental Bleeding Index (EIBI)

Caton & Polson (1985) developed the Eastman Interdental Bleeding Index (EIB). A wooden interdental cleaner is inserted between the teeth from the facial aspect, depressing the interdental tissues 1 to 2 mm. This is repeated four times and the presence or absence of bleeding within 15 s is recorded. Considering the overall high levels of reliability between and within examiners, this method would be suitable for use in clinical trials and epidemiological studies (Bliden et al., 1992).

Quantitative Gingival Bleeding Index (QGBI)

In 1985, Garg & Kapoor formulated a quantitative gingival bleeding index. This index takes into consideration the magnitude of blood stains covering tooth brush bristles on

brushing and squeezing gingival tissue units in a segment, with one score for entire one segment (canine to canine, or left or right pre-molars and molars in maxillary or mandibular arches – six segments in total). The criteria scores are:

0 - no bleeding on brushing; bristles free from blood stains;

1 - slight bleeding on brushing; bristle tips stained with blood;

2 - moderate bleeding on brushing; about half of bristle length from tip downwards stained with blood;

3 - Severe bleeding on brushing; entire bristle length of all bristles including brush head covered with blood.

Bleeding is generally immediately evident on the bristles of the brush; however, 30 seconds were allowed for reinspection of each segment. According with authors, this index has good reproducibility, reliability, objectivity and simplicity of use.

Modified Gingival Index (MGI)

The Modified Gingival Index (MGI), devised by Lobene et al. (1986), introduced changes in the criteria of the Gingival Index (Löe and Silness, 1963) through a non-invasive (no probing) and resetting the rating for mild and moderate inflammation. The following criteria are adopted:

0 = absence of inflammation;

1 = mild inflammation or with slight changes in color and texture but not in all portions of gingival marginal or papillary;

2 = mild inflammation, such as the preceding criteria, in all portions of gingival marginal or papillary;

3 = moderate, bright surface inflammation, erythema, edema and/or hypertrophy of gingival marginal or papillary;

4 = severe inflammation: erythema, edema and/or marginal gingival hypertrophy of the unit or spontaneous bleeding, papillary, congestion or ulceration.

Gingival units as well as the calculation of the index follow the same criteria described in GI.

Bleeding on Interdental Brushing Index (BOIB)

In 2010 Hofer et al. developed the Bleeding on Interdental Brushing Index (BOIB). This index is performed by inserting a light interdental brush placed buccally, just under the contact point and guided between the teeth with a jiggling motion, without force. Bleeding is scored as either present or absent, for each interdental site, after 30 s.

Table 1. Gingival Indices

Index Name	Author (s)	Year	Instrument	Graded response	Time delay (Seconds)
PMA index	Schour and Massler	1947	Probe	0-5	Not stated
Gingival Index (GI)	Loe and Silness	1963	Probe	0-3	Not stated
Sulcus Bleeding Index (SBI)	Muhlemann and Son	1971	Probe	0-5	Not stated
Gingival Bleeding index (GBI)	Carter and Barnes	1974	Unwaxed dental Floss	Yes/No	Not stated (30' reinspection)
Gingival Bleeding index (GBI)	Ainamo and Bay	1975	Probe	Yes/No	10
Papillary Bleeding Index	Muhlemann	1977	Probe	0-4	Not stated

Modified Papillary Bleeding Index	Barnett et al.	1980	Probe	0-3	0-30
Bleeding Time Index (BTI)	Nowicki et al	1981	Probe	0-4	0-15
Eastman Interdental Bleeding Index	Caton and Polson	1985	Wooden interdental cleaner	Yes/no	0-15
Quantitative Gingival Bleeding Index	Garg and Kapoor	1985	Tooth Brush	0-3	Not stated
Modified Gingival Index	Lobene et al.	1986	Visual	0-4	N/A
Bleeding on interdental Brushing index (BOIB)	Hofer et al.	2010	Interdental brush	Yes/no	30

2.2 Digital Imaging System

Digital imaging in oral care began with efforts focused on quantifying dental plaque and later on tooth color measurement and eventually on to gingival health assessments (Soder et al 1993).

The development of the digital camera coupled with image analysis software yielded the first attempts to develop an imaging system capable of capturing pictures of disclosed plaque and automated measurement of plaque coverage. The first attempts utilized a red coat-disclosing agent and did not enable the analysis software to distinguish between plaque on the teeth, gingival plaque and gingiva due to the close red color of the three entities (MacGregor, 1987).

Photographic methods have also been developed to assess gingival overgrowth. Standardized photographic view can be evaluated against a reference set of photographs that define various degrees of gingival overgrowth (Hefti et al. 1994).

Another study that used photography was the one done by Ellis et al. (5), they used photographs of patient's teeth that were projected onto a large screen. These were

assigned a score indicating the encroachment level of the anterior papilla from 0 to 3. This method was applied to the labial surfaces of the anterior teeth. The scoring system was based on that developed by Seymour et al. 1985 whereby the score 0 indicated no health problems, 1 defined slight granulation of appearance of the papilla, 2 indicated slight gingival encroachment over the tooth surface less than a quarter of the tooth width and 3 described severe encroachment over a quarter of the tooth width. This method used basic image analysis, but relied upon the three-stage scoring applied to each of 10 papillae regions.

Smith et al. 2008 showed that digital imaging had excellent reliability for both intra- and inter-examiner measurements. The authors concluded that digital photography technique proved a reliable method for investigating changes in gingival redness.

3. Aim, Hypothesis and Objectives

3.1 Aim

This study aimed to investigate and validate the quantitative abilities of digital imaging technique in experimental gingivitis conditions before and after clinical intervention.

3.2 Hypothesis:

There is no difference between digital imaging and examiner based gingival grading in assessing gingivitis clinical characteristic using an experimental gingivitis model.

Digital gingivitis image analysis positively associates with clinical parameters in an experimental gingivitis model.

3.3 Objective

The objective of this study was to compare a Digital Gingivitis Image Analysis (DGIA) method and examiner-based gingival grading in assessing experimental anterior gingivitis.

4. Study design and methods

4.1 Study Design

The study was approved by the University of Connecticut Health Institutional Review Board (IRB number 14-046-1).

This study was a Randomized, Controlled, Parallel Design, Examiner-Blinded Clinical Trial

4.2 Population:

Systemically health participants with clinical signs of facial anterior gingivitis were recruited based on the criteria below.

Inclusion Criteria

In order to be included in the study, each subject must:

1. Be at 18-65 years of age;
2. Provide written informed consent prior to participation and to be given a signed copy of the informed consent form;
3. Be in good general health as determined by the investigator/designee based on a review of the health history/update for participation in the study;
4. Agree not to participate in any other oral/dental product studies during the course of this study;

5. Agree to delay any elective dentistry (including dental prophylaxis) and to report any non-study dentistry performed on them for the duration of the study;
6. Agree to refrain from the use of any non-study oral care products once assigned to treatment;
7. Agree to return for all scheduled visits and follow study procedures;
8. Have all 12 anterior teeth free of crowns, veneers or large restorations, and
9. Have mild to moderate gingivitis with at least 3 facial anterior bleeding sites (teeth #6-11 and 22-27).

Exclusion Criteria

Subjects were excluded when there was evidence of:

1. Severe periodontal disease, as characterized by purulent exudate, generalized mobility, and/or severe recession;
2. Any condition, which required antibiotic premedication for the administration of a dental prophylaxis;
3. Self-reported pregnancies or intent to become pregnant during the course of the study and nursing females;
4. Having atypical discoloration or pigmentation in the gingival tissue;
5. Having fixed orthodontic appliances;
6. Any diseases or conditions that could be expected to interfere with the subject safely completing the study; or
7. Inability to undergo imaging or other study procedures.

Participants were randomly allocated in two different groups. During the experimental phase subjects in the test group were instructed to abstain from all forms of oral hygiene. Subjects in the control group continued their oral hygiene.

4.3 Experimental Design and Procedures

The study consisted of 2 phases:

1. Oral hygiene phase (Day -14 through Day 0),
2. Induced gingivitis phase (Day 0 through Day 21).

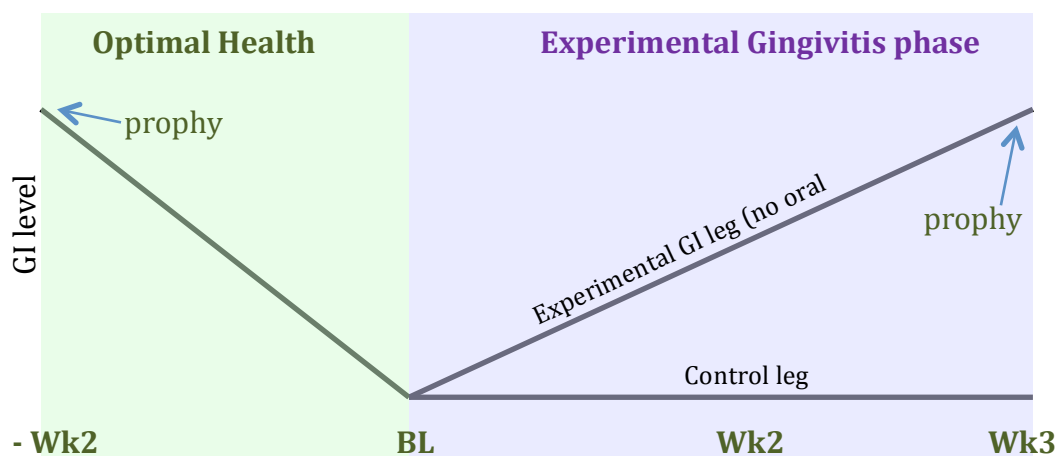


Fig. 1 Study visits: - Week 2 visit, Baseline visit, Week 2 visit and Week 3 visit.

During the oral hygiene phase subjects underwent an oral prophylaxis at Day -14 and were instructed to brush 2x daily with a power toothbrush.

At the beginning of the experimental gingivitis phase, subjects were randomized to either a test group or a control group. Subjects in the test group were asked to abandon all other oral hygiene for the duration of the phase. Subjects in the control group were instructed to

brush 2x daily with a power toothbrush for the duration of the phase. Subjects received an oral prophylaxis at the conclusion of the experimental gingivitis phase.

Digital Gingivitis Image (DGIA) analysis was performed on images of facial anterior gingival regions and whole mouth gingivitis including facial anterior regions were assessed using Loe-Silness examinations at Day -14, Day 0, Day 14 and Day 21.

Table 2: Study Procedures

Procedure	Day -14	Day 0	Day 14	Day 21
Informed Consent	X			
Medical History Review	X			
Demographics	X			
Inclusion/Exclusion Criteria	X			
Continuance Criteria		X	X	X
Oral Status Interview	X	X	X	X
Oral Examination	X	X	X	X
Digital Gingival Imaging	X	X	X	X
Loe-Silness GI Exam	X	X	X	X
Dental Prophylaxis	X			X
Take-Home Product Distribution	X	X*		
Product Usage/Hygiene Instructions	X	X		
Compliance Check		X	X	X
AEs		X	X	X
Take-Home Kit Return		X		X*
General Comments	X	X	X	X
Subject Accountability				X

**Control group only*

Oral Hygiene Phase:**Day —14**

Subjects were asked to read and sign duplicate copies of the informed consent form. Subjects were given one signed copy of the informed consent form and the other signed copy will be maintained as site source documentation. Personal medical history Information was reviewed and retained as site source documentation. Demographic information and entrance criteria were assessed. An Oral Status Interview was conducted, and an Oral Soft Tissue examination was performed. Subjects brushed their teeth with water and a flat-trim manual brush, followed by digital imaging. A gingivitis exam (Loe-Silness) was performed. After receiving a full-mouth oral prophylaxis, each subject was given electric toothbrush and cavity protection toothpaste and received written and verbal instructions to use these products 2x day for the duration of the Oral Hygiene phase. Subjects were instructed to bring all study products to the next visit.

Day 0

This visit was the conclusion of the oral hygiene phase and was the baseline visit of the experimental gingivitis phase. See Day 0 (Baseline) of the Experimental Gingivitis Phase for details.

Induced Gingivitis Phase:**Day 0 (Baseline)**

Subjects brought all study products to the visit. Continuance criteria were assessed. An Oral Status Interview was conducted. Subjects received an Oral Soft Tissue exam.

Subjects brushed their teeth with water and a flat-trim manual brush, and a digital image of their facial anterior teeth was taken. A Loe-Silness gingivitis exam was performed.

Subjects were randomized to treatment and received written and verbal instructions. During this 21-day phase subjects in the test group were instructed to abstain from all forms of oral hygiene for the duration of the phase. Subjects in the control group continued using an electric toothbrush and a cavity protection toothpaste 2x day for the duration of the phase and were asked to bring all study products to the next visit.

Day 14

Subjects brought all study products to the visit. Continuance criteria were assessed. An Oral Status Interview was conducted. Subjects received an Oral Soft Tissue exam. Subjects brushed their teeth with water and a flat-trim manual brush, and a digital image of their facial anterior teeth was taken. A Loe-Silness gingivitis exam was performed. Subjects in the control group were asked to bring all study products to the next visit.

Day 21

Subjects brought all study products to the visit. Continuance criteria were assessed. An Oral Status Interview was conducted. Subjects received an Oral Soft Tissue exam. Subjects brushed their teeth with water and a flat-trim manual brush, and a digital image of their facial anterior teeth was taken. A Loe-Silness gingivitis exam was performed. Subjects in the test group received a full-mouth oral prophylaxis. Subjects in the control group were offered an option of receiving an oral prophylaxis. A subject accountability form was completed and subjects were dismissed from the study.

Statistical Methods Planned in the Protocol and Determination of Sample Size

Given that this was a pilot, feasibility study, the sample size was based on logistical considerations and not power analysis. Therefore, up to 50 subjects were enrolled in the study (25 per group).

Blinding, Labeling, and Shipping Plan

Oral Hygiene Phase (all subjects) and Induced Gingivitis phase (control group only):

Subjects received a cavity protection dentifrice, and a rechargeable powered toothbrush. These items were shipped in bulk to the investigational site and distributed to the subjects by site personnel. Digital timers were sent to the investigational site in bulk for site personnel to supervise brushing.

Continuance Criteria

Subjects were excluded from the study or the analysis if they:

1. Became pregnant or developed an intercurrent medical condition that put the subject at increased risk or invalidates the results of the study;
2. Received a dental prophylaxis outside of study;
3. Used antibiotics any time during the study;
4. Used any oral care products other than assigned study products;
5. Participated in any other oral/dental product study since their last study visit, or
6. Were unable to comply with study instructions for any reason.

Efficacy and Safety Variables

Löe-Silness Gingivitis Index

The Löe-Silness GI was used to evaluate the gingivitis based on color, consistency, and bleeding on probing. The entire dentition, with the exception of the third molars, was evaluated. For each tooth, six gingival areas (distobuccal, buccal, mesiobuccal, mesiolingual, lingual, and distolingual) were scored using adequate light, a mouth mirror, and a periodontal probe. Prior to scoring, the teeth and gingiva were air dried as required to provide adequate visibility. The probe was inserted about 1mm into the gingival sulcus and passed from interproximal to interproximal. One aspect (either facial or lingual) of each tooth in a quadrant was first “skimmed” and then graded before passing to the next quadrant. Each of the six tooth surfaces was given a score of 0-3. Summing the scores and dividing by the number of scorable sites examined determined a subject’s full mouth GI score. Scoring criteria were as follows:

Table 3 Löe-Silness GI scoring criteria

Score	Criteria
0	Normal gingiva
1	Mild inflammation — slight change in color, slight edema. No bleeding on probing.
2	Moderate inflammation — redness, edema, and glazing. Bleeding on probing.
3	Severe inflammation marked redness, edema. Ulceration. Tendency to spontaneous bleeding.
8	Unscorable tooth

9	Missing tooth
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Due to the nature of the measurement, the Löe-Silness GI assessed both inflammation and bleeding. In an effort to assess bleeding, we constructed a Bleeding Score (BS) variable in a categorical manner: score 1 would signify bleeding, when the GI score was either a 2 or 3, and score 0 would signify bleeding absence when GI score was 0 or 1. A subject's full mouth bleeding score was determined by summing the Bleeding Scores over all sites examined. Facial anterior GI and bleeding scores were calculated in a similar manner described above using marginal sites near teeth #6-11 and 22-27, with the exception of facial distal sites at teeth #6, 11, 22, and 27.

Digital Gingival Imaging

This system consisted of a high-resolution digital camera, equipped with a lens with a linear polarizer to permit cross-polarized light or similar optical system (Fig. 2). Two 150-watt lights located on each side of a camera provided the lighting. The unit was connected to a personal computer, which recorded the images for later computerized analysis. Prior to daily use, the system was calibrated to assure proper operation. Additionally, a color standard was centered and imaged every hour, and then was removed prior to imaging subjects. Each image was collected in a darkened room. The subject sat on a stool in front of a chin rest used to hold the head still.



Fig. 2 Camera System

The subject placed the chin on the chin rest and then positioned two sterile plastic retractors into the mouth to retract the lips and cheeks. The subject was instructed to use the retractors to retract the lips and cheeks (toward the ears) as far as possible. The incisal edges of the front teeth were placed together and centered in the camera (Fig. 3). Prior to exposure the subject was instructed to draw air through the teeth and to position the tongue away from the teeth so that the tongue was not visible. The image was taken of the lips, teeth and gums only; the whole face was not visible in the image. Each image was saved in a file with the subject ID number.

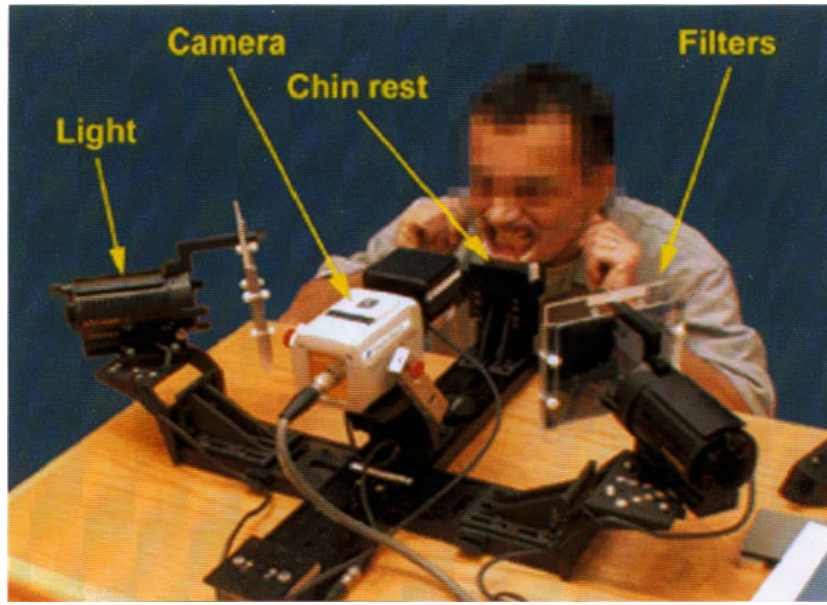


Fig. 3 Physical setup of system for capturing images.

The color of gingival tissue within 1 to 2 mm of the gingival margin of the facial anterior dentition was calculated for each subject at each visit. Color was measured as Red Green-Blue (RGB) pixel values from the images and it was also converted to CIE $L^*a^*b^*$ values. For CIE $L^*a^*b^*$, L^* represented the lightness scale, $+a^*$ was red to $-a^*$ was green, and $+b^*$ was yellow to $-b^*$ blue (Fig. 4). The color change between visits was also calculated. Additional subject-level measurements were calculated for specific regions of gingiva, e.g., interdental papilla, different distances from the gingival margin, etc. Lastly, the examiner assessed the gingivitis from the digital images and compared them to the gingival color values.



Fig. 4 Color Classification.

Oral Soft Tissue (OST) Examination:

Assessment of the oral soft tissues was conducted via a visual examination of the oral cavity and perioral area utilizing a standard dental light, dental mirror, and gauze. The structures examined include the gingiva (free and attached), hard and soft palate, oropharynx/uvula, buccal mucosa, tongue, floor of the mouth, labial mucosa, mucobuccal/mucolabial folds, lips, and perioral area.

Statistical and Analytical Plans

Statistical Efficacy Analyses:

Summary statistics (e.g., means, standard deviations, frequencies, etc.) of the demographic characteristics and gingivitis assessments were calculated for each treatment group and visit.

For each gingival assessment, comparisons between visits were investigated using repeated measures analysis, and treatment comparisons between groups were used for analysis of covariance with baseline as a covariate. A multivariate analysis was used to investigate the relationship between facial anterior examiner-graded gingivitis scores and gingival color assessments. Statistical tests were two-sided using a 5% significance level.

Statistical Safety Analyses:

The safety data was summarized with respect to tooth sensitivity and oral irritation. All adverse events were summarized overall and by treatment group.

Method of Assigning Subjects to Treatment Groups

Prior to the Baseline visit, subjects were randomly assigned in approximately equal numbers to one of the two treatment groups. The randomization was balanced for the Day -14 Löe-Silness scores (both whole mouth and facial anterior areas), age, gender, and gingival imaging color values. A statistician that was not in the study carried out the randomized assignment procedure. Subjects who resided in the same household were assigned to the same treatment group.

5. Results

5.1 Gingival Index Results

After the screening process and hygiene phase, 49 subjects were randomized to treatment although only 48 subjects began the induced gingivitis treatment phase (1 subject was randomized but dropped before Day 0). Forty-eight subjects completed the study, and 47

subjects were evaluable during the induced gingivitis treatment phase since one subject had severe recession. The research was a randomized, parallel group Experimental Gingivitis study with a 2-week hygiene phase receiving a dental prophylaxis and the control products described below (Fig 5). During the 3-week induced gingivitis phase, subjects were randomized to one of the following two treatment groups:

Treatment during the Induced Gingivitis Phase:

- Control/Brush: Continue twice daily with toothpaste (0.243% Sodium Fluoride) with a rechargeable electric toothbrush, or
- Test/None: Abandon all oral hygiene.

The 47 evaluable subjects ranged in age from 19 to 64 years with an average of 32.1 years. 53% of the subjects were female, and for ethnicity 55% of the subjects were Caucasian, 17% Hispanic, 13% African American, and the rest other ethnicities. Groups were well balanced ($p>0.4$) with respect to demographics characteristics and Day 0 gingivitis response.

Phases of Study:

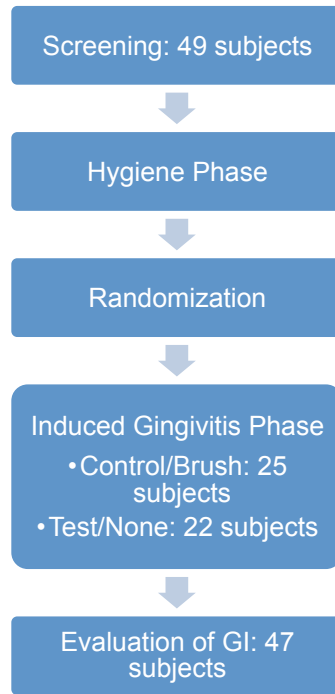


Fig. 5 Phases of the study from day -14 (screening) to day 21

The Bleeding response and LSGI were similar for both groups at day 0 (Table 3 and 4).

Table 3. Bleeding Analysis: Day 0

Region	Visit	Hygiene Group	N	Mean (SD)	p-value For group Balance
Whole Mouth	Day -14	None	22	66.091 (25.829)	
Whole Mouth	Day -14	Brush	25	66.640 (21.089)	
Whole Mouth	Day 00	None	22	37.818 (19.355)	0.4244
Whole Mouth	Day 00	Brush	25	42.840 (23.329)	
Facial	Day -14	None	22	13.182	

Anterior				(5.179)	
Facial Anterior	Day -14	Brush	25	10.440 (4.583)	
Facial Anterior	Day 00	None	22	7.773 (5.117)	0.4199
Facial Anterior	Day 00	Brush	25	6.640 (4.310)	

Tab. 3 Groups were balanced at Day 0 with respect to mean # of Bleeding Sites Day -14.

Red: Test group / no hygiene; Blue: Control group

Table 4. Loe-Silness Gingival Index Analysis: Day 0

Region	Visit	Hygiene Group	N	Mean (SD)	p-value For group Balance
Whole Mouth	Day -14	None	22	1.4121 (0.1787)	
Whole Mouth	Day -14	Brush	25	1.3997 (0.1255)	
Whole Mouth	Day 00	None	22	1.1833 (0.1690)	0.6461
Whole Mouth	Day 00	Brush	25	1.2059 (0.1649)	
Facial Anterior	Day -14	None	22	1.4129 (0.1613)	
Facial Anterior	Day -14	Brush	25	1.3263 (0.1432)	
Facial Anterior	Day 00	None	22	1.1231 (0.2545)	0.4918
Facial Anterior	Day 00	Brush	25	1.0750 (0.2159)	

Tab 4. Groups were balanced at Day 0 with respect to mean Loe-Silness GI. Day -14

Red: Test group / no hygiene; Blue: Control group

Statistically significant ($p < 0.0001$) differences between groups were demonstrated at Days 14 and 21 for both numbers of Bleeding Sites and LSGI in each region of whole mouth and facial anterior sites, (See the table 4 and 5 below for ANCOVA adjusted means, standard errors, means, and p-values.)

Table 5. End Point Analysis Bleeding

Region	Visit	Hygiene Group	Mean (SD)	p-value	% Reduction of Brush Adj. Mean vs. No Hygiene
Whole Mouth	Day 14	None	104.409 (4.786)	<0.0001	67.49
Whole Mouth	Day 14	Brush	35.240 (4.487)	<0.0001	
Whole Mouth	Day 21	None	90.591 (5.229)	<0.0001	60.27
Whole Mouth	Day 21	Brush	36.840 (4.904)	<0.0001	
Facial Anterior	Day 14	None	21.000 (1.149)	<0.0001	78.09
Facial Anterior	Day 14	Brush	4.320 (1.078)	<0.0001	
Facial Anterior	Day 21	None	17.591 (0.997)	<0.0001	76.38
Facial Anterior	Day 21	Brush	4.000 (0.935)	<0.0001	

Tab 5. Statistically significant ($p < 0.0001$) differences between groups at Days 14 and 21 for number of bleeding sites in each region of whole mouth and facial anterior sites
Red: Test group / no hygiene; Blue: Control group/ Brushing

Table 6. End Point Analysis Gingival Index

Region	Visit	Hygiene Group	Mean (SD)	p-value	% Reduction of Brush Adj. Mean vs. No Hygiene
Whole Mouth	Day 14	None	1.6439 (0.0550)	<0.0001	67.49
Whole Mouth	Day 14	Brush	0.9740 (0.0516)	<0.0001	
Whole Mouth	Day 21	None	1.5609 (0.0383)	<0.0001	60.27
Whole Mouth	Day 21	Brush	1.1662 (0.0359)	<0.0001	
Facial Anterior	Day 14	None	1.6566 (0.0672)	<0.0001	78.09
Facial Anterior	Day 14	Brush		<0.0001	
Facial Anterior	Day 21	None	17.591 (0.997)	<0.0001	76.38
Facial Anterior	Day 21	Brush	4.000 (0.935)	<0.0001	

Tab 6. Statistically significant ($p < 0.0001$) differences between groups at Days 14 and 21 for LSGI in each region of whole mouth and facial anterior sites
 Red: Test group / no hygiene; Blue: Control group/ Brushing

Subject Level analysis

Bleeding response

During the study we observed a trend on the bleeding response. Subjects included on the brushing group had a constant reduction on bleeding (whole mouth / facial anterior) while subjects that abandoned oral hygiene had a significant increase on these parameters.

Whole Mouth

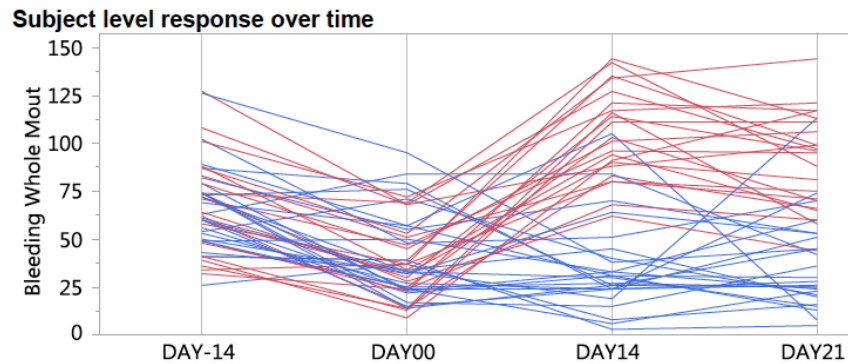


Fig. 6 Bleeding whole mouth from day -14 (screening) to day 21

Red: Test group / no hygiene
Blue: Control group / Brushing

Facial Anterior

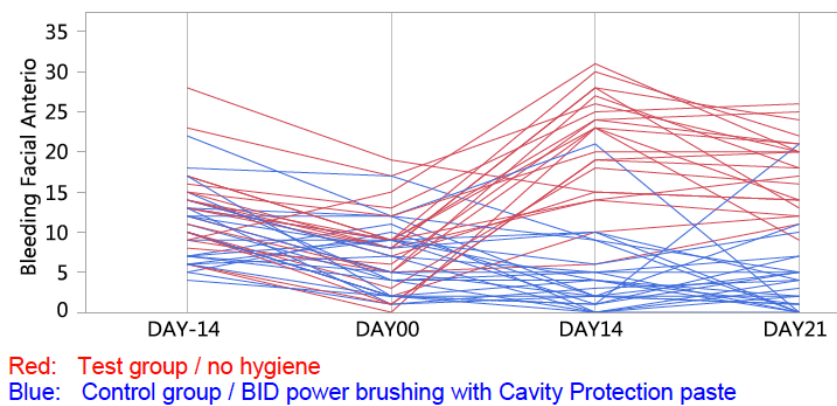


Fig. 7 Bleeding Facial Anteriors from day -14 (screening) to day 21

Red: Test group / no hygiene
Blue: Control group / Brushing

Similar response was observed regarding LSGI. Subjects participating in the brushing group had a significant reduction of GI meanwhile subjects participating in the non brushing group experienced a increased on GI

Gingival Index

LSGI Whole mouth

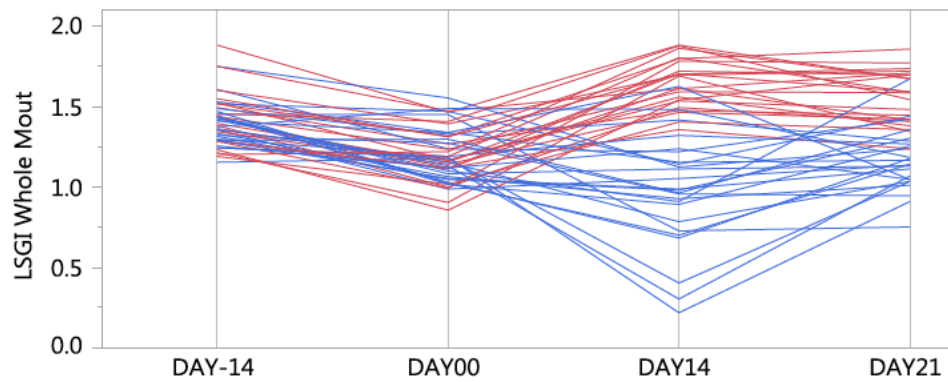
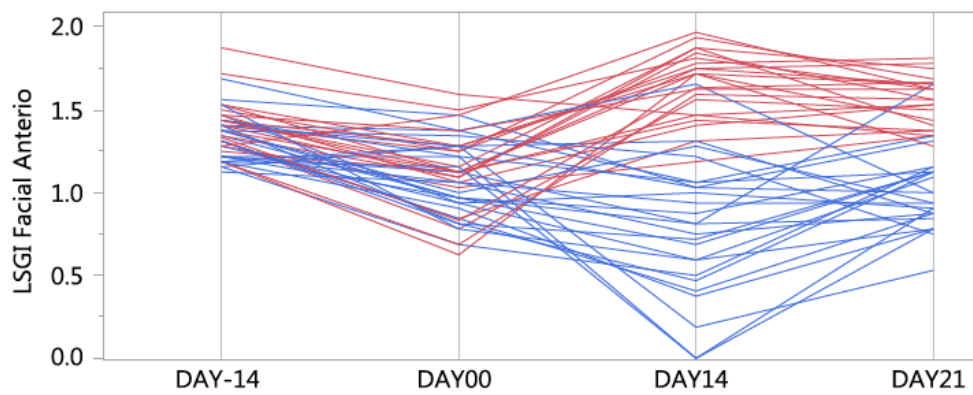


Fig. 8 LSGI whole mouth from day -14 (screening) to day 21

Red: Test group / no hygiene
Blue: Control group / Brushing

LSGI Facial Anteriors



Red: Test group / no hygiene
Blue: Control group / BID power brushing with Cavity Protection paste

Fig. 9 LSGI Facial Anteriors from day -14 (screening) to day 21

Red: Test group / no hygiene
Blue: Control group / Brushing

Gingival Image Analysis:

For the gingival image analysis we used Delta E2000. This is a measurement of a distance or difference between colors. The International Commission on Illumination (CIE) calls their distance metric ΔE^*_{ab} (also called ΔE^* , dE^* , dE , or "Delta E"). Delta E is a metric for understanding how the human eye perceives color difference. The term *delta* comes from mathematics, meaning change in a variable or function. The suffix *E* references the German word *Empfindung*, which broadly means sensation (Sharma, G. 2004).

Different studies have proposed different ΔE values that have a JND (just noticeable difference). Unempirically, a value of '1.0' is often mentioned, but in a recent study, Mahy et al. (1994) assessed a JND of 2.3 ΔE . However, perceptual non-uniformities in the underlying CIELAB color space prevent this and have led to the CIE's refining their definition over the years, leading to the superior (as recommended by the CIE) 1994 and 2000 formulas. These non-uniformities are important because the human eye is more sensitive to certain colors than others. A good metric should take this into account in order for the notion of a "just noticeable difference" to have meaning. Otherwise, a certain ΔE that may be insignificant between two colors that the eye is insensitive to may be conspicuous in another part of the spectrum (Lindbloom et al 2011)

Using the imaging system we noticed the marked changed in color from day 0 to day 21. We observed 2 units of color change ($\Delta E_{2000}= 2.41$) for non-brushing group and 1.4 units

change on brushing group ($\Delta E_{2000} = 1.41$). These changes were consistent with the clinical measurements.

↓ ΔE_{2000} gingival color change

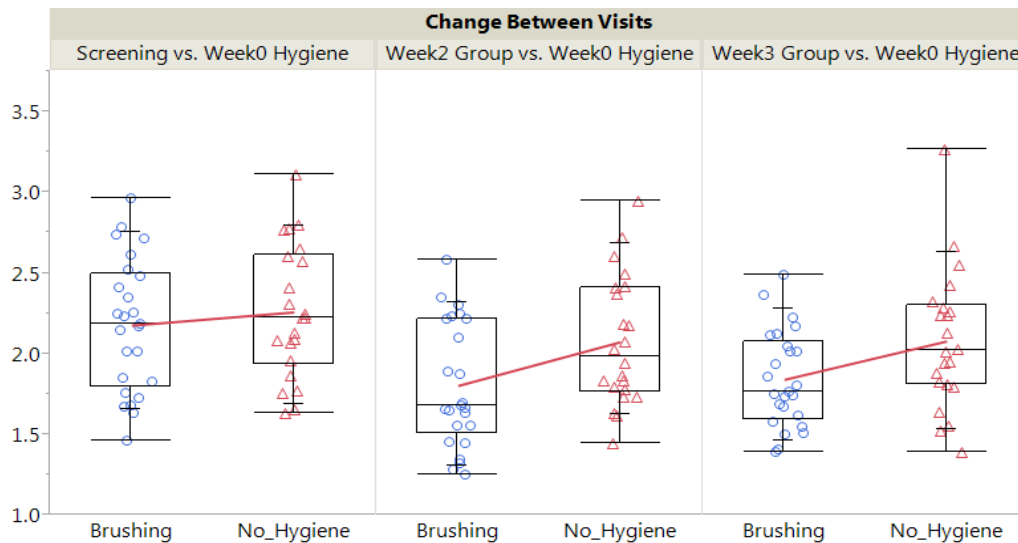


Fig. 10 ΔE_{2000} gingival color change from day -14 to day 21

Subjects in brushing group experienced less inflammation, which in the image analysis is translated in less redness and less bleeding.

Brushing Group:

Subject 1061 Electric toothbrush

$\Delta E_{2000} = 1.45$

Week 0

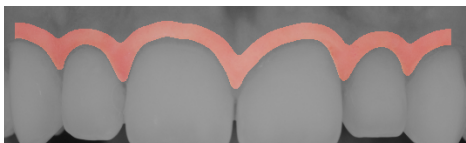


Fig 11

Week 2:



Fig.12

On the other hand subjects in the non-brushing group had more redness and bleeding by week 2. The changes can be appreciated on Fig 11-14

No hygiene:

Subject 1053 No Hygiene $\Delta E_{2000} = 2.41$

Week 0

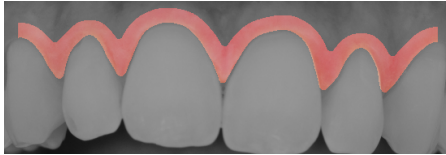


Fig 13

Week 2:

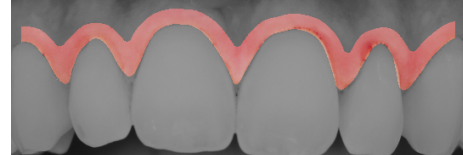


Fig 14

5. Discussion:

The present study was initiated to assess whether there was any difference between digital imaging and examiner based gingival grading in assessing gingivitis clinical characteristic using an experimental gingivitis model.

Using the imaging system we were able to notice marked changes in color from day 0 to day 21. We observed 2 units of color change ($\Delta E_{2000} = 2.41$) for non-brushing group and 1.4 units change on brushing group ($\Delta E_{2000} = 1.41$). These changes were consistent with the clinical measurements.

Statistically significant ($p < 0.0001$) differences between groups were demonstrated at Days 14 and 21 for the number of Bleeding Sites in each region of whole mouth and facial anterior sites. In this respect, the results of the present study are in accordance with previous experience with the experimental gingivitis model (Løe et al. 1965, Santi & Bral 1998, Majola et al. 2000, Brunet et al. 2001, Miranda et al. 2001)

The percentage mean reduction of the Brush group relative to the No Hygiene group varied from 60 to 78% for Bleeding. The reductions in gingival bleeding and gingivitis obtained in the brushing group are within the range of values seen in previous studies. A similar result was reached by McClanahan and Bartizek (2002) in a 3-month gingivitis clinical study. They examined the relationship between the baseline gingival bleeding sites and the 3-month gingival bleeding sites for the study population. Subjects with at least 40 gingival bleeding sites at baseline demonstrated 4.2% gingival index and 15% gingivitis severity index reduction on the brushing group.

It can be accepted that due to imaging restrictions there may be some subjectivity in the redness assessment due to selection of the area of interest, although the reliability results proved sound. Another limitation of the study is that this method can only assess the anterior part of the oral cavity and often there is severe inflammation in the posterior part. Previous reports included use of two quadrants (Deinzer et al. 1999), one quadrant (Putt et al. 1993, van der Weijden et al. 1994) and any number of contiguous teeth (Bosman & Powell 1977, Matheny et al. 1993, Daly & Highfield 1996), extending over one (Bosman & Powell 1977, Daly & Highfield 1996) or two quadrants (Matheny et al. 1993). The results of partial-mouth (“localized”) experimental gingivitis studies have always been similar to the results of full-mouth studies, making the “localized” assessment equivalent to the original full-mouth one.

The photographic method described proved to be highly acceptable to patients. The technique was very simple, and showed good agreement with clinical scores.

Since periodontal diseases are primarily inflammatory in nature, the ability to detect inflammatory lesions in gingival tissues is essential for the diagnosis and monitoring of

changes in gingival status. Clinical indices provide a means of converting observed clinical data into numerical data for statistical analysis.

Barnett in 1996, presented data indicating that non-invasive and invasive gingival indices contain both subjective and objective aspects to their use and the evidence does not support the assumption that invasive indices are truly objective. Therefore, utilizing a pure visual index in assessing gingivitis can be an alternative to an invasive index.

To our knowledge, this is the first study conducted in the US assessing gingivitis with digital imaging and comparing it with examiner based gingival exam. From a practical point of view, digital imaging system provides motivation to the patients giving pictorial indication of their changing periodontal / gingival state as well as providing objective data to match those changes. Similarly, permanent database of images could be created to objectively assess reliability, reviewing results or for further research studies. More importantly, the method does not require qualified clinicians unlike many of the existing indices. Nevertheless, image analysis is limited to recording of color change and area only and as such traditional clinical assessments and examinations would still need to be undertaken.

We can conclude that the photographic method described above provides an objective, easy-to-use method of evaluating the severity of gingival inflammation. The method requires no specialized skills apart from a familiarity with the photographic equipment. The procedure is non-invasive, can be scored blind and the initial data can be collected by personnel other than dental practitioner.

The technique is thus appropriate for large-scale population studies to determine severity and prevalence of gingivitis. However, where more repeatable scoring on a small scale is

required, the clinical measurement method (LSGI) should be considered the optimum choice of technique.

6. Conclusion

Digital Gingivitis Image Analysis (DGIA) provides an objective, easy-to-use method of evaluating gingival inflammation. Digital gingivitis image analysis positively associates with clinical parameters in an experimental gingivitis model. The technique is thus appropriate for large-scale population studies to determine severity and prevalence of gingivitis.

7. References

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